Special 510(k) Summary

as required by section 807.92(c).

MAR 2 0 2014

Camber Spine Technologies
Diagon Oblique Cage
K 134038

Revised	March 20, 2014
Submitter:	Camber Spine Technologies 90 S. Newtown Street Rd., Suite #10 Newtown Square, PA 19073
Contact Person	Dan Pontecorvo President Phone: 484-420-4219 Fax: (484) 318-8031 Email: delvalsyn@comcast.net
Trade Name	Diagon Oblique Cage
Common Name	Oblique Cage
Device Class	Class II
Classification Name and Number	Intervertebral Fusion Device With Bone Graft, Lumbar 21 CFR 888.3080
Classification Panel:	Orthopedic
Product Code	MAX
Predicate Devices	Camber Spine Technologies TLS 5.0 Interbody Cage (K121254)
Device Description	Camber Spine Technologies, Diagon Oblique Cage is a device for interbody fusion of the anterior column of the spine. These cages are hollow so that bone can grow through the device, fusing the adjacent bony surfaces. Camber Spine Technologies, Diagon Oblique Cage is a hollow device with texture on two opposing convex sides, and is offered in various lengths, widths, heights and shapes. Camber

	Spine designed the Camber Spine Technologies, Diagon Oblique Cage to be placed through a transforaminal or posterior approach and to address vertebrae in the lumbosacral region of the spine. The Camber Spine Technologies, Diagon Oblique Cage is made from Implant grade (PEEK) per ASTM2026 (Solvay Zeniva ZA-500) which is a radiolucent material with embedded tantalum x-ray markers as specified in ASTM F560.
Indications for Use	The Camber Spine Technologies Diagon Oblique Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Camber Spine Technologies Diagon Oblique Cage is to be used with autologous bone graft and implanted via an open transforaminal or posterior approach. Camber Spine Technologies Diagon Oblique Cage implants are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Statement of Technological Comparison and Fundamental Scientific Technology	Camber Spine Diagon Oblique Cage and its predicate device have the same indications for use, similar design, same materials, technology principles of operation and test results.

Nonclinical Test Summary	The following tests were performed to demonstrate that the Camber Spine Technologies Diagon Oblique Cage is substantially equivalent to other predicate devices. • Static Compression Test per ASTM F2077 • Static Compression Shear ASTM F2077 • Subsidence Test per ASTM F2267 • Static Expulsion Test The results of these studies showed that the Camber Spine Technologies Diagon Oblique Cage met the acceptance criteria.
Clinical Test Summary	n/a

Conclusion	Camber Spine Technologies Diagon Oblique Cage and its predicate device have the same indications for use, similar design, and test results. Both devices are manufactured using materials with a long history of use in orthopaedic implants.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 20, 2014

Camber Spine Technologies
Mr. Daniel Pontecorvo
President & CEO
90 South Newtown Street Road, Suite 10
Newtown Square, Pennsylvania 19073

Re: K134038
Trade/Device Name: Camber Spine Technologies Diagon Oblique Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: February 19, 2014
Received: February 21, 2014

Dear Mr. Pontecorvo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K134038

Device Name
Camber Spine Technologies Diagon Oblique Cage

Indications for Use *(Describe)*
The Camber Spine Technologies Diagon Oblique Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Camber Spine Technologies Diagon Oblique Cage is to be used with autologous bone graft and implanted via an open transforaminal or posterior approach.

Camber Spine Technologies Diagon Oblique Cage implants are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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